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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,015	08/23/1999	Carsten Korth	DT-3073	2058

7590 08/26/2002  
SIDLEY AUSTIN BROWN & WOOD, LLP  
787 SEVENTH AVENUE  
NEW YORK, NY 10019

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/26/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/380,015

Applicant(s)

KORTH ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 40-76 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's election with traverse of Group I in Paper No. 11 in response to the Election/Restriction requirement of Paper No. 6 is acknowledged. The traversal is on the grounds there is unity of invention in the newly submitted claims 40-76 of October 17, 2001 (Paper No. 10). Applicants have cancelled all previous claims and added new claims 40-76. Upon review and reconsideration of the new claims the following new Restriction/Election requirement is made.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 40-49, 51\*, 52, 53, 54, 67, 68 and 72, drawn to a monoclonal antibody that recognizes the disease state prion protein, a hybridoma cell line and a test kit comprising the monoclonal antibody.

Group II, claim(s) 50 and 51\*, drawn to an anti-idiotypic antibody.

Group III, claim(s) 55, 56, drawn to a recombinant protein that encodes an antibody from the hybridoma cell line.

Group IV, claim(s) 57-60, 65, 66, drawn to an expression vector encoding the bovine prion protein and a cell line for the expression of the vector.

Group V claim(s) 61-64, drawn to a method of producing an antibody and a method of a method of producing a hybridoma cell line.

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Group VI, claim(s) 69, 70 and 71, drawn to a method detecting disease specific prion protein or an antibody to the disease specific prion protein.

Group VII, claim(s) 73, 74 and 76\*, drawn to a method of therapy using a monoclonal antibody.

Group VIII, claim(s) 75 and 76\*, drawn to a method of therapy using a prion protein.

Note: Claim 51 is drawn to a hybridoma cell line. The claim reads on Group I as well as Group II, these hybridoma cell lines are specific depending on whether they produce an antibody that recognizes the prion protein or whether they produce the anti-idiotypic antibody. Claim 51 will be examined to the extent that it reads on either Group I or Group II. The claim does not link these inventions of Group I and Group II.

Note: Claim 76 is a "use" claim, the claim has been interpreted as a method and will be examined to the extent that it reads on a method of using antibodies Group VII or a method of using the prion protein Group VIII. The claim does not link the inventions of Group VII and VIII.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I, II, III, V, VI and VII appears to be the monoclonal antibody that recognizes the disease specific prion protein. Group IV and VIII are distinct from the other groups as they are drawn to the prion protein and are thereby not linked by the antibody. Prusiner et al. (U.S. Pat. No. 5,846,533) teach the production of monoclonal antibodies that recognize the disease specific form of the prion protein (see claims, figure 12, and examples 11, 13 and 18). Therefore, the technical feature linking the inventions does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of group I is considered to be a monoclonal antibody that recognizes the disease specific prion protein.

The special technical feature of group II is considered to be an anti idiotypic antibody directed against antibodies that bind the prion protein.

The special technical feature of group III is considered to be a recombinant protein sequence derived from the hybridoma cell lines producing the monoclonal antibody.

The special technical feature of group IV is considered to be an expression made up of DNA encoding the prion protein and a cell line comprising the expression vector.

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The special technical feature of group V is considered to be a method of producing a hybridoma cell line.

The special technical feature of group VI is considered to be a method of detecting disease specific prion protein.

The special technical feature of group VII is considered to be a method of therapy using a monoclonal antibody.

The special technical feature of group VIII is considered to be a method of therapy using a prion protein.

Accordingly, groups I-VIII are not so linked by the same or corresponding technical feature as to form a single general inventive concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Paul Scott on August 22, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made due to the unavailability of Applicant's client.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

The examiner can normally be reached M-F, 8:30 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in cursive script, appearing to read 'Ulrike Winkler', is written above the printed name.

Ulrike Winkler, Ph.D.